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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,575	04/14/2000	FRANCIS JAMES ROURKE	7042-R	9622

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EXAMINER

ANDERSON, CATHARINE L

ART UNIT	PAPER NUMBER
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3761

MAIL DATE	DELIVERY MODE
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09/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/529,575

Applicant(s)

ROURKE ET AL.

Examiner

C. Lynne Anderson

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31, 32, 36, 42-44, 46, 48, 52 and 53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31, 32, 36, 42-44, 46, 48, 52 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 June 2007 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 31-32, 36, 42-44, 46-48, and 52-53 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31, 32, 36, 42-44, 46, 48, and 52-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roe (5,607,760) in view of Cadwell (5,874,164).

With respect to claims 31, 32, 36, 42 and 44, Roe discloses all aspects of the claimed invention with the exception of the protease inhibitor being pentamidine and present in the amount of 0.0001-30% by weight. Roe discloses a disposable wearable article comprising a liquid permeable topsheet 520, a liquid impervious backsheet 530,

Art Unit: 3761

and an absorbent core 540. The topsheet comprises a delivery system in the form of a lotion, as disclosed in column 3, lines 3-5. The lotion includes an antibacterial, as disclosed in column 23, lines 24-31.

Cadwell teaches the application of an antibacterial protease inhibitor, pentamidine, to the topsheet of an absorbent article, as described in column 55, lines 16-19 and 28. It would have been obvious to one of ordinary skill in the art at the time of invention to provide the lotion of Roe with pentamidine, as taught by Cadwell, to yield the predictable result of providing the lotion with antimicrobial activity.

The lotion of Roe is applied to the topsheet in an amount that will impart the desired therapeutic benefits of the lotion without saturating the topsheet, as disclosed in column 24, lines 1-12. It would therefore have been obvious to one of ordinary skill in the art at the time of invention to apply the lotion in an amount such that the protease inhibitor would be present in the article in a range of about 0.0001% to about 30% by weight because there would have been a reasonable expectation of success that such an amount would provide a therapeutic benefit without requiring so much lotion that the topsheet would be saturated.

The IC_{50} is defined in the instant specification on page 7 as being dependant on the concentration of protease inhibitor and the rate of substrate cleavage of the protease inhibitor. The rate of substrate cleavage is dependent on the individual protease inhibitor, and pentamidine is disclosed in the specification as being a suitable protease inhibitor. Therefore, pentamidine, when present in the claimed concentration,

Art Unit: 3761

inherently has an IC_{50} of about 500 μM or less, no more than 100 μM , and as a result is capable of producing at least a 10% reduction in substrate hydrolysis by a protease.

With respect to claim 43, the lotion is transferable to the skin of a wearer, as disclosed in column 25, lines 25-27.

With respect to claim 46, the deliver system contains the protease inhibitor as molecules, or particles, as disclosed by Cadwell in column 55, line 37.

With respect to claim 48, the lotion is applied to the wearer-contacting surface of the topsheet, as disclosed in column 25, lines 25-27.

With respect to claims 52 and 53, the lotion is applied in a plurality of stripes with a region of the topsheet not containing lotion, as shown in figure 2.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 6,355,858 discloses the use of protease inhibitors in absorbent materials.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Lynne Anderson whose telephone number is (571) 272-4932. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

WA

cla

September 20, 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

